



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference M4266-PCT		FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/EP2007/003810		International filing date (day/month/year) 30.04.2007	Priority date (day/month/year) 19.05.2006	
International Patent Classification (IPC) or national classification and IPC INV. A61C13/00				
Applicant Materialise Dental N.V.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>7</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of <u>5</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand 2008-03-19		Date of completion of this report 14.11.2008		
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized officer Chabus, Hervé Telephone No. +31 70 340-2684 		

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-20 as originally filed

Claims, Numbers

1-30 filed with telefax on 19.03.2008

Drawings, Sheets

1/7-7/7 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

5. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 70.2 (e)).

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 8, 9

because:

☒ the said international application, or the said claims Nos. 8, 9 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*).

☒ no international search report has been established for the said claims Nos. 8, 9

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See separate sheet for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-7, 10-30</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	<u>1-7, 10-30</u>
	No: Claims	
Industrial applicability (IA)	Yes: Claims	<u>1-7, 10-30</u>
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

Re Item III.

The subject matter of claims 8 and 9 has not been searched since it relates to a method of treatment of the human or animal body by surgery (Rule 39.1 (iv) and Rule 67.1 (iv) PCT). By using a depth gauge, and in particular a hypodermic needle in order to measure the thickness of the soft tissue, the tissue is penetrated and altered, and this is considered as a surgical step.

Re Item V.

1. Reference is made to the following documents:

D1: US 5562448 A (MUSHABAC DAVID R [US]) 8 October 1996 (1 996-10-08)

D2: WO 2004/064660 A (TACTILE TECHNOLOGIES LLC [US]; WEINSTEIN URIEL [IL]; YOHAI YUVAL [IL];) 5 August 2004 (2004-08-05) cited in the application

D3: US-Bi -6 319 006 (SCHERER FRANZ [DE] ET AL) 20 November 2001 (2001-11-20) cited in the application

D4: DE 100 36 027 AI (SCHREIBER HANS [DE]) 10 January 2002 (2002-01-10)

2. INDEPENDENT CLAIM 1

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

- 2.2 The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document):

A method for creating a personalized digital planning environment for simulation of dental implant placement from

(i) a digitised representation of an intra-oral surface anatomy of a patient including at least a part of the dental arch (e.g. video signals, column 10 lines 35 to 56, and column 24 lines 53 to 55),

(ii) a point wise digital representation of bone surface in the region of and around potential dental implant receptor sites (column 24 lines 53 to 65), and

(iii) a two-dimensional dental X-ray image of the potential dental implant receptor sites (column 25 lines 14 to 17), the method comprising:

- mapping the two-dimensional dental X-ray image of the potential dental implant receptor sites along at least part of a dental arch of the digitized intra-oral surface anatomy (column 10 lines 57 to 67, and column 27 lines 27 to 64),
- constructing a three-dimensional surface model of the bone at the potential dental implant receptor sites based on the at least point-wise digital representation of bone surface (column 24 lines 53 to 65), and
- generating a single digital project file comprising at least the digitized representation of the intra-oral surface anatomy of the patient, the mapped two-dimensional dental X-ray image and the three-dimensional surface model of the bone at the potential dental implant receptor sites. (Column 24 line 35 to column 25 line 62).

2.3 The subject-matter of claim 1 therefore differs from this known method in that:

- the three-dimensional surface model of the bone is based on a point wise digital representation of soft-tissue thickness and in that
- the method includes the step of mapping the dental X-ray image (11) along at least part of a curved surface following the dental arch (1) by folding the dental X-ray image (11) along said curved surface.

2.4 While making a point wise measurement of bone surface location is equivalent to making a point wise measurement of soft-tissue thickness especially when using a stylus or probe member as in document D1, the cited documents do not hint at folding the dental X-ray image along a curved surface following the dental arch for mapping the dental X-ray image on the 3D intra-oral image.

Consequently, the subject-matter of claim 1 involves an inventive step in the sense of Article 33(3) PCT.

3 INDEPENDENT CLAIMS 18, 19, 20, 21 and 30

3.1 Independent claim 18 refers to a computer program product for executing any of the methods as claimed in any one of the claims 1-17 when executed on a computing device associated with a simulation device for simulation of dental implant placement. For the same reason as mentioned in paragraph 2.4, the

subject-matter of independent claim 18 involves an inventive step.

- 3.2 Claim 19 which refers to a machine readable data storage device storing the program product of claim 19 and claim 20 which refers to a method of transmission of the same involve also an inventive step.
- 3.3 The computer system as defined in independent 21 includes the corresponding means for performing the steps of the method as specified in claim 1. Therefore, the subject-matter of independent claim 21 involves an inventive step in the sense of Article 33(3) PCT.
- 3.4 The subject matter of claim 30 basically contains all the features of claim 1 with in addition the steps of generating the data (i), (ii) and (iii) which are used in the method of claim 1. The same reasoning applies as for claim 1.

Therefore the subject matter of claim 30 also involves an inventive step in the sense of Article 33(3) PCT.

DEPENDENT CLAIMS 2-7, 10-17, 22-29

4. Claims 2-7,10-17 are dependent on claim 1 and therefore satisfy the requirements of the PCT with respect to novelty and inventive step.
5. 22-29 are dependent on claim 21 and therefore satisfy the requirements of the PCT with respect to novelty and inventive step.

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AMENDED CLAIMS

1. A method for creating a personalized digital planning environment for simulation of dental implant placement from (i) a digitised representation of an intra-oral surface anatomy of a patient including at least a part of the dental arch, (ii) an at least point-wise digital representation of soft tissue thickness in the region of and around potential dental implant receptor sites (2), and (iii) a two-dimensional dental X-ray image of the potential dental implant receptor sites (2), the method comprising:
 - mapping the two-dimensional dental X-ray image of the potential dental implant receptor sites (2) along at least part of a dental arch (1) of the digitized intra-oral surface anatomy,
 - constructing a three-dimensional surface model of the bone at the potential dental implant receptor sites (2) based on the at least point-wise digital representation of soft tissue thickness, and
 - generating a single digital project file comprising at least the digitized representation of the intra-oral surface anatomy of the patient, the mapped two-dimensional dental X-ray image and the three-dimensional surface model of the bone at the potential dental implant receptor sites,characterised in that the method includes the step of mapping the dental X-ray image (11) along at least part of a curved surface following the dental arch (1) by folding the dental X-ray image (11) along said curved surface.
2. Method according to claim 1, wherein the digitized representation of an intra-oral surface anatomy is investigated for possible dental implant receptor sites (2).
3. Method according to claim 2, wherein digitized representation of an intra-oral surface anatomy is for the entire dental arch (1) of the upper jaw (12) and/or lower jaw (13).
4. Method according to any one of the previous claims, wherein the digitized representation of an intra-oral surface anatomy is a surface scan of the mouth of the patient.

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5. Method according to any one of claims 1 to 3, wherein the digitized representation of an intra-oral surface anatomy is obtained from an impression of the upper jaw (12) and/or lower jaw (13), whereby this impression is used to digitally capture spatial coordinates of the intra-oral surface.
6. Method according to any one of the previous claims, wherein the digital representation of the soft tissue (7) is obtained via statistical information from an expert system.
7. Method according to any one of claims 1 to 5, the soft tissue (7) having a thickness, wherein digital representation of the soft tissue (7) is obtained via local measurements of the thickness of the soft tissue.
8. Method according to claim 7, wherein the local measurements of the thickness of the soft tissue (7) are obtained by using a depth gauge.
9. Method according to claim 8, wherein the depth gauge comprises at least one hypodermic needle (5).
10. Method according to claim 7, wherein local measurements of the thickness of the soft tissue (7) are obtained from ultrasound measurements.
11. Method according to any one of the previous claims, wherein mapping the dental X-ray image along at least part of the dental arch (1) comprises indicating corresponding points on the dental X-ray image and on the intra-oral surface anatomy.
12. Method according to any one of the previous claims, wherein mapping the dental X-ray image along at least part of the dental arch (1) comprises non-uniform stretching of the X-ray image.
13. Method according to any of the previous claims, wherein mapping the dental X-ray image along at least part of the dental arch (1) includes linear scaling of the X-ray image in the apical-coronal-direction of the patient.
14. Method according to any one of the previous claims, wherein mapping the dental X-ray image along at least part of the dental arch (1) includes non-linear scaling of the X-ray image in the horizontal direction.

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15. Method according to any of the previous claims, wherein constructing a three-dimensional surface model of the bone at the potential dental implant receptor sites (2) is performed by offsetting the soft tissue thickness inwardly in a direction towards the jawbone.
16. Method according to any of the previous claims, wherein generating a single digital project file comprising information obtained in the previous steps is performed by combining obtained digital information in a single digital project visualisable on a display screen.
17. Method according to any of the previous claims, furthermore comprising importing the digital project file into implant planning software.
18. Computer program product for executing any of the methods as claimed in any one of the previous claims when executed on a computing device associated with a simulation device for simulation of dental implant placement.
19. Machine readable data storage device storing the computer program product of claim 18.
20. A method of transmission of the computer program product of claim 18 over a local or wide area telecommunications network.
21. A computer system for creating a personalized digital planning environment for simulation of dental implant placement from a digitised representation of an intra-oral surface anatomy of a patient including at least a part of the dental arch, an at least point-wise digital representation of soft tissue thickness in the region of and around potential dental implant receptor sites (2), and a two-dimensional dental X-ray image of the potential dental implant receptor sites (2), the system comprising:
 - means for mapping the two-dimensional dental X-ray image of the potential dental implant receptor sites (2) along at least part of a dental arch (1) of the digitised intra-oral surface anatomy,
 - means for constructing a three-dimensional surface model of the bone at the potential dental implant receptor sites (2) based on the at least point-wise digital representation of soft tissue thickness, and
 - means for generating a single digital project file comprising at least the digitized representation of the intra-oral surface anatomy of the

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patient, the mapped two-dimensional dental X-ray image and the three-dimensional surface model of the bone at the potential dental implant receptor sites,

characterised in that the means for mapping the two-dimensional dental X-ray image (11) along at least part of a dental arch (1) comprises means for folding the dental X-ray image (11) along at least part of a curved surface following the dental arch (1).

22. A computer system according to claim 21, wherein the means for mapping the two-dimensional dental X-ray image comprises means for investigating for possible dental implant receptor sites (2).
23. A computer system according to claim 21 or 22, wherein the means for mapping the two-dimensional dental X-ray image comprises means for performing a surface scan of the mouth of a patient.
24. A computer system according to any of claims 21 to 23, wherein the means for mapping the two-dimensional dental X-ray image comprises means for performing linear scaling of the X-ray image in the apical-coronal direction of the patient.
25. A computer system according to any of claims 21 to 24, wherein the means for mapping the two-dimensional dental X-ray image comprises means for performing non-linear scaling of the X-ray image in the horizontal direction.
26. A computer system according to any one of claims 21 to 25, the soft tissue (7) having a thickness, wherein the means for constructing a three-dimensional surface model of the bone at the potential dental implant receptor sites (2) comprises means for local measurement of the thickness of the soft tissue (7).
27. A computer system according to any one of claims 21 to 26, wherein the means for constructing a three-dimensional surface model of the bone at the potential dental implant receptor sites (2) comprises means for performing offsetting the soft tissue thickness inwardly in a direction towards the bone.
28. A computer system according to any one of claims 21 to 27, wherein the means for generating a single digital project file comprises means for

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combining obtained digital information in a single digital project visualisable on a display screen.

29. A computer system according to any one of claims 21 to 28, furthermore comprising means for importing the digital project file into implant planning software.

30. A method for creating a personalized digital planning environment for simulation of dental implant placement, the method comprising:

- digitising intra-oral surface anatomy of a patient,
- generating an at least point-wise digital representation of soft tissue thickness in the region of and around potential dental implant receptor sites (2),
- taking a two-dimensional dental X-ray image (11) of the potential dental implant receptor sites (2) and mapping it along at least part of a dental arch (1) of the digitised intra-oral surface anatomy,
- constructing a three-dimensional surface model of the bone at the potential dental implant receptor sites (2) based on the at least point-wise digital representation of soft tissue thickness, and
- generating a single digital project file comprising information obtained in the previous steps,

characterised in that the method includes the step of mapping the dental X-ray image (11) along at least part of a curved surface following the dental arch (1) by folding the dental X-ray image (11) along said curved surface.